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August 19, 2024

Honorable Judge James Donato
San Francisco Courthouse, Courtroom 11, 19th Floor
450 Golden Gate Avenue, San Francisco, CA 94102

Re: *Nektar Therapeutics v. Eli Lilly and Company*, 23-cv-3943-JD (N.D. Cal.)

Dear Judge Donato:

Nektar's latest motion to compel is part of its maximalist discovery strategy designed to impose burden on Lilly. See 8/9/2024 Nektar Letter Br. (ECF 91). Far from "withholding relevant documents," Lilly has attempted for months to work with Nektar to identify targeted, workable discovery on the relevant issues in this case, attending 12 discovery conferences and exchanging over 150 pages of discovery letters. To date, Lilly has produced nearly 150,000 documents, continues to diligently review the hundreds of thousands of documents it has collected, and will soon make additional productions of tens of thousands of documents. The discovery Lilly has agreed to produce covers the waterfront on the relevant issues in this case. It broadly falls into two categories.

First, Lilly has agreed to produce documents related to nearly every aspect of its development of REZPEG. Nektar has not argued—because it cannot—that there are any gaps in Lilly's production that prevent it from evaluating Lilly's efforts to develop REZPEG.

Second, Lilly agreed to produce documents that allow Nektar to compare Lilly's efforts on other drugs in Lilly's portfolio—so-called "comparators"—in areas where Nektar alleges Lilly's efforts fell short on REZPEG. The commercially reasonable efforts clause in the License Agreement limits relevant comparators to drugs at a "similar stage of development" on an "Indication-by-Indication" basis. Based on this prescription, Lilly offered to produce documents related to Nektar's allegations for **every drug** in Lilly's pipeline—**12 other development programs**¹—that was at the same "stage of development" for the same "indication" as REZPEG in the relevant time period. Given the number of drugs—and the fact that the Agreement does not allow for additional comparators—the Court rightly observed that discovery on "10 or 11 [drugs] seems like more than enough just to show that [Lilly] did something else where they didn't do here." Civil Minutes (ECF 77), at 10:2-4.

For these potentially comparable drugs, Lilly has agreed to produce documents related to the relevant issues in Nektar's complaint. Nektar alleges Lilly's efforts on REZPEG were not commercially reasonable in three respects: (1) overseeing the contractor that made a math error in Phase 1 psoriasis and atopic dermatitis ("AtD") trials; (2) the design of a Phase 2 AtD trial; and (3) the design of a Phase 2 lupus trial. Based on these allegations, Lilly has agreed to produce documents

¹ Lilly has offered to produce documents for a total of 12 other Lilly drugs developed between 2015 and 2023, in the same indications and phases as the four REZPEG trials Nektar takes issue with in its complaint. After the hearing, Nektar said it was no longer interested in three of those drugs.

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about its design of the comparator drug trials and its oversight of contractors—as well as more general information about its efforts like budgets and resource allocations—for each of the comparators.

Tellingly, Nektar has not been able to explain why it needs more documents to evaluate its claims. At the last hearing, for example, Nektar could not “just tell [the Court] what [it] want[s]” if it had a “magic carpet ride to victory” on its motion. Civil Minutes (ECF 77), at 13:16-19. That is because Lilly has already agreed to an expansive scope of discovery. Nektar’s present motion to compel new, irrelevant categories of documents and new, irrelevant drugs goes far beyond the parties’ agreement and the allegations in Nektar’s complaint. The Court should reject it.

I. Nektar’s Request for Irrelevant Phases of Development Should Be Denied.

In addition to the potentially comparable drugs for which Lilly has already offered to produce documents, Nektar asks the Court to compel the same discovery for drugs that reached Phase 3 clinical trials. This request sweeps in massive amounts of discovery on two additional drugs, as well as numerous irrelevant trials for the agreed comparators.

This discovery is plainly irrelevant under the License Agreement, which required Lilly to use the “effort, expertise and resources normally used” on its comparable drugs “at a *similar stage* of development[.]” License Agmt., Art. I (emphasis added). The parties included this provision for good reason, given a manufacturer’s efforts to develop drugs vary depending on the drug’s stage of development. There are three “stages” of clinical trial development: Phase 1, Phase 2, and Phase 3. Phase 3 trials cost orders-of-magnitude more than the earlier stages, given their much larger size and the fact that drugs at this stage are close to regulatory approval. Comparing Lilly’s efforts on a Phase 3 clinical trial to Lilly’s efforts on smaller-scale, earlier-stage trials makes no sense.

That expressly dispenses with Nektar’s requests. Lilly *only* conducted Phase 3 trials on the two additional drugs Nektar seeks, tabalumab and lebrikizumab (which it acquired after Phase 2 was complete, and therefore played no role in decisions for the Phase 2 study). Nektar argues lebrikizumab is relevant because a document Lilly produced, LLY00000607, shows that “Rezpeg’s trials were ‘deprioritized’ due to a lebrikizumab trial.” 8/9/2024 Nektar Letter Br. (ECF 91), at 1. That mischaracterizes the document. All it says is Lilly was enrolling patients in a Phase 3 lebrikizumab trial in 2020 before enrolling patients in the two Phase 1 trials, given Phase 1 trials are comprised of dozens of patients and Phase 3 trials are comprised of thousands. It is also legally irrelevant, given Nektar has no allegations that Lilly did not sufficiently enroll those REZPEG trials.

II. The Additional Documents Nektar Requests Are Irrelevant and Unworkable.

Lilly is also producing many broad categories of documents for the agreed-upon comparators like: (1) its engagement and oversight of contractors that perform statistical analysis like the ones that oversaw the REZPEG trials; (2) trial protocols, statistical analysis plans (“SAPs”), specifications, and clinical study reports; (3) trial designs and endpoints; (4) enrollment for Phase 2 lupus trials; (5) severity, frequency, and prevalence of injection site reactions; (6) probability of technical and regulatory success; (7) drug investigator’s brochures; and (8) budgets and spending.

Nektar’s motion frankly ignores what Lilly has already agreed to do. For example, it argues that “Lilly has refused to produce any documents showing whether Lilly verified that efficacy calculations for the Other Drugs were accurate.” 8/9/2024 Nektar Letter Br. (ECF 91), at 2. Not so. Lilly expressly agreed to “produce documents sufficient to show *efforts Lilly took to ensure accurate*

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statistical analysis of any phase 1 study for [AtD] or psoriasis sponsored by Lilly[.]” Lilly’s Resp. to Nektar’s RFP 43 (emphasis added). Lilly also agreed to produce SAPs, specifications, and third party oversight plans for every drug it developed in Phase 1 AtD and psoriasis from 2015 to 2023.

Nektar also misleadingly downplays the burden of its requests by framing them as seeking “discrete categories of documents” that could be satisfied by non-custodial, central document collections. In reality, many of these requests would require new and extraordinarily burdensome investigation and both custodial and non-custodial collections, review, and production. The burden of doing so cannot be overstated and is wholly unwarranted. For REZPEG alone, Lilly collected and reviewed hundreds of thousands of custodial and non-custodial documents, including from 15 custodians, to make its nearly 150,000-document production to date. None of the additional discovery Nektar seeks is proportional to the needs of the case given the amount of discovery Lilly is already producing on its other drugs, the massive burden this additional requested discovery would impose, and the lack of connection Nektar’s requested “categories of documents” have to its complaint—which only challenges two Phase 2 trial designs and a contractor’s math error in two Phase 1 trials.

Lilly addresses each new category Nektar requests in turn.

Forecasts and Commercial Analyses. Nektar requests “Lilly’s forecasts and assessments of the market potential for the Other Drugs.” 8/9/2024 Nektar Letter Br. (ECF 91), at 2. However, forecasts and commercial analyses for other Lilly drugs have no bearing on whether Lilly exercised commercially reasonable efforts for the statistical analysis of the Phase 1 trials or the design of the Phase 2 trials. Nektar tellingly points to no allegations or facts to suggest otherwise—nor could it. None of Lilly’s decisions were allegedly premised on forecasts of REZPEG relative to other drugs in its portfolio, especially given Lilly does not begin commercial analyses until a drug nears Phase 3—which REZPEG never did.

Go/No-Go Decisions. Nektar has completely rewritten its initial request for “Documents related to ‘go/no-go decisions’ and Lilly’s decisions to move forward with, or not move forward with, or prioritize or deprioritize with respect to funding, budgets, development, or pursuit of clinical trials,” after Lilly repeatedly explained its irrelevance. 7/9/2024 Kargan Ltr., at 3. Now, Nektar asks for the “criteria that Lilly used to determine whether to continue development.” The only allegation related to Lilly’s decision to “continue development” concerns REZPEG’s failure to meet the Phase 2 lupus trial endpoints. And Lilly has agreed to produce documents showing endpoints in Phase 2 lupus trials.

Collaboration Agreements. Lilly’s collaborations on other drugs are unrelated to whether it used CRE on the challenged aspects of the four REZPEG trials, and Nektar does not claim otherwise.

Management Presentations & Minutes. Nektar seeks “management presentations” or “board minutes” related to the comparator drugs. But Nektar does not explain why it needs Lilly to produce these commercially sensitive documents for other drugs, given Lilly has already agreed to produce documents related to the relevant topics Nektar identifies, such as clinical trial materials that show trial design, enrollment, endpoints, and injection site reactions. Nektar identifies no incremental benefit—beyond a desire to fish through sensitive documents and to impose burden on Lilly. And to the extent “management presentations” and “minutes” touch on REZPEG, Lilly is producing those.

Lilly respectfully requests that the Court deny Nektar’s request.

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Respectfully submitted,

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